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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/551,603	01/20/2006	Thomas C. Schulz	18377-0067	8027

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EXAMINER

SAJJADI, FEREDOUN GHOTB

ART UNIT	PAPER NUMBER
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1633

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/551,603	Applicant(s) SCHULZ ET AL.	
	Examiner Fereydoun G. Sajjadi	Art Unit 1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 November 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-18 and 31 is/are pending in the application.
- 4a) Of the above claim(s) 10-18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-9 and 31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>11/26/2007</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Status

Applicants' response of November 26, 2007, to the non-final action dated July 25, 2007 has been entered. Claim 3 has been cancelled. Claims 1, 2, 4-18 and 31 are pending in the Application. Claims 1, 4, 7 and 31 have been amended. No claims were newly added. Claims 10-18 remain withdrawn from consideration, with traverse. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144). See MPEP § 821.01.

Claims 1, 2, 4-9 and 31 are currently under examination.

Information Disclosure Statement

The information disclosure statement filed 11/26/2007 has been considered and indicated as such on Form PTO/SB/08a.

Response to Priority

The previous office action dated July 25, 2007 indicated that the disclosure of the prior-filed Provisional Application, No. 60/459,090, fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application, because the '090 Application does not include Example 19 or a disclosure of the abnormal karyotypes in bulk passaged HESCs.

Applicants disagree and argue that the currently pending claims as amended are sufficiently supported and enabled by Provisional Application No. 60/459,090 because, the specification describes the SSEA4 selection and bulk passaging of cells with trypsin treatment. Further arguing that this cell population inherently has the characteristic of having an abnormal karyotype as a result of this passaging technique. Applicants' arguments have fully considered but are not found persuasive.

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In response, it is noted that Example 19 of the instant specification discloses that the cells showed abnormal karyotypes only following 32 or more passages. The abnormal karyotypes including various autosomal trisomies. Thus, an artisan of skill would not be apprised of cellular aneuploidy as a result of specific passage number and conditions, or the nature of said aneuploidy, and would therefore not recognize that Applicants had possession of cells carrying specific karyotype abnormalities that included autosomal trisomies of chromosomes 1, 7, 8, 12, 14 and 17, as instantly claimed.

Therefore, the effective filing date of the instant application with regards to amended claims 1, 2, 4-9 and 31 is the filing date of PCT/US04/10121, filed 3/31/2004.

Response to Claim Rejections - 35 USC § 112- Second Paragraph

Claims 1-9 and 31 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite, in previous office action dated July 25, 2007.

In view of Applicants' amendment of claims 1 and 31, deleting the limitation of "pluripotent" with regard to the aneuploid embryonic stem cell culture, thus obviating the ground for rejection, the rejection is hereby withdrawn.

Claim Rejections - 35 USC § 112-Lack of Enablement

Claim 1-9 and 31 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. Applicants' cancellation of claim 3 renders its rejection moot. The rejection set forth on pp. 4-7 of the previous office action dated July 25, 2007 is maintained for claims 1, 2, 4-9 and 31 for reasons of record.

Applicants' amendment of claims 1 and 31 to recite that the human embryonic cells are aneuploid and not pluripotent, in part addresses the grounds for rejection.

With regard to the issue of how to use human cells that are karyotypically abnormal, Applicants argue that the cells may be used to study cancer and early transforming genetic events leading to tumorigenesis, citing the post-filing art of Baker et al. Applicants' arguments have fully considered but are not found persuasive.

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Applicants should note that MPEP 2164.05(a) states, the specification must be enabling as of the filing date. A later dated publication cannot supplement an insufficient disclosure in a prior dated application to make it enabling. Publications dated after the filing date providing information publicly first disclosed after the filing date generally cannot be used to show what was known at the time of filing. *In re Gunn*, 537 F.2d 1123, 1128, 190 USPQ 402,405-06 (CCPA 1976); *In re Budnick*, 537 F.2d 535, 538, 190 USPQ 422, 424 (CCPA 1976).

As stated in MPEP 2164.01, "The test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation." Applicants' statement that the instantly claimed cells may be used to study cancer and early transforming genetic events, amounts to an invitation to an artisan of skill to carry out further basic research to study the properties of the claimed product itself or the mechanisms in which the material is involved, thus constituting further undue experimentation. As cells carrying abnormal karyotypes are to be avoided in the potential use of these cells as therapeutics, the usefulness of the instantly claimed abnormal ES cells remains unclear.

Therefore, the rejection of claims 1, 2, 4-9 and 31 is maintained for reasons of record and the foregoing discussion.

Response to Claim Rejections - 35 USC § 102

Claims 1-2 and 31 were rejected under 35 U.S.C. 102(e) as being anticipated by Carpenter (U.S. Patent No.: 6,833,269; filed May 31, 2001), in previous office action dated July 25, 2007.

Applicants' have amended claims 1 and 31, replacing the limitation of "pluripotent" with aneuploid embryonic stem cell culture. As Carpenter does not teach human aneuploid embryonic stem cells, the previous rejection is hereby withdrawn. Accordingly, Applicants' arguments are rendered moot.

Claim 31 was rejected under 35 U.S.C. 102(b) as being anticipated by Odorico et al. (Stem Cells 19:193-204; 2001), in previous office action dated July 25, 2007.

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Applicants' have amended claims 1 and 31, replacing the limitation of "pluripotent" with aneuploid embryonic stem cell. As Odorico does not teach human aneuploid embryonic stem cells, the previous rejection is hereby withdrawn. Accordingly, Applicants' arguments are rendered moot. However, the claim is subject to a new rejection over the prior art as indicated below.

New Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Applicants' claim amendments have necessitated the following new grounds of rejection.

Claim 31 is newly rejected under 35 U.S.C. 102(a) as being anticipated by Rosler et al. (Developmental Dynamics 229:259-274, 2004).

Claim 31 is drawn to a human aneuploid embryonic stem cell produced by antibody selection and maintenance in culture; and is thus a product by process claim.

Applicants should note that the rejection has not been extended to instant claim 1, as the claim encompasses cells expressing nestin, that are at least partially differentiated along the neuronal path.

MPEP 2112.01 states: "Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a *prima facie* case of either anticipation or obviousness has been established. *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977)." MPEP 2113 further states: "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the

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prior product was made by a different process.” *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

Rosler et al. teach human embryonic stem cells maintained in continuous culture for over 1 year (Title and Abstract). The authors additionally teach: “The karyotype analysis demonstrated that approximately 20% of individual cultures showed some degree of aneuploidy.” (p. 270). Therefore, each and every element and limitation of claim 31 in the present invention is anticipated and effectively addressed by Rosler et al. The examiner further maintains that the office does not have the facilities for examining and comparing applicant’s product with the product of the prior art in order to establish that the product of the prior art does not possess the same material, structural and functional characteristics of the claimed product. In the absence of factual evidence to the contrary, the burden is upon the applicant to prove that the claimed products are functionally different than those taught by the prior art and to establish patentable differences. See *Ex parte Phillips*, 28 USPQ 1302, 1303 (BPAI 1993), *In re Best*, 562, F.2d 1252, 195 USPQ 430 (CCPA 1977) and *Ex parte Gray*, 10 USPQ2d 1922, 1923 (BPAI 1989). The claiming of a new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977); *In re Spada*, 15 USPQ2d 1655, Federal Circuit, 1990. See also MPEP § 2112.01 with regard to inherency and product-by-process claims.

Conclusion

Claims 1-9 and 31 are not allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. The claims are drawn to the same invention claimed earlier in the application and would have been finally rejected on the grounds and art of record in the next Office Action if they had been entered earlier in the application. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fereydoun G. Sajjadi whose telephone number is (571) 272-3311. The examiner can normally be reached on 6:30 AM-3:30 PM EST.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Fereydoun G. Sajjadi, Ph.D.
Examiner, AU 1633



/Anne Marie S. Wehbe/
Primary Examiner, A.U. 1633